K002794

DEC - 6 2000

EXHIBIT 2

HyperTec Inc.
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Contact: Travis Fromme, President
September 6, 2000

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Model 5000 Multiplace" Hyperbaric Therapy Systems.
   Classification Name: Hyperbaric Chamber 73CBF
   Common/Usual Name: Hyberbaric Chamber

2. Equivalent legally marketed device: This product is similar in design and identical in function to the Perry Baromedical SIGMA Plus/II Multiplace Hyperbaric Chamber, K983648.

3. Indications for Use (intended use) The following indications are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS). The UHMS is the primary source of information for diving and hyperbaric medicine physiology worldwide.

- Air or Gas Embolism
- Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
- Clostridal Myositis and Myonecrosis (Gas Gangrene)
- Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias
- Decompression Sickness
- Enhancement of Healing in Selected Problem Wounds
- Exceptional Blood Loss (Anemia)
- Intracranial Abscess
- Necrotizing Soft Tissue Infections
- Osteomyelitis (Refractory)
- Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
- Skin Grafts & Flaps (Compromised)
- Thermal Burns"

4. Description of the Device: The HyperTec Model 5000 Multiplace Hyperbaric System has been designed for safe, easy operation and maintenance. It consists of a double lock pressure vessel and control system; both mounted on a chassis. The chamber pressure vessel is comprised of a carbon steel cylinder with two end heads divided by an intermediate head to form two locks (Inner and Outer Lock). As part of this vessel,

a 32" diameter manway in an intermediate head, a 32" diameter manway in an external head, one 3" diameter viewport, and three 12" diameter viewports are included. The control console is located on the side of the chamber, where it is readily accessible. All chamber components are designed for ease of operation and require minimum maintenance. The chamber can be pressurized with compressor or high pressure bottle supplied air which has been sufficiently filtered for breathing gas applications. During treatment, the patients breathe from the air or oxygen supplied to a treatment hood. The oxygen supplied to the hood must also meet the filtration requirements for breathing gases.

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Perry Baromedical SIGMA Plus/II Multiplace Hyperbaric Chamber, K983648.	HyperTec Model 5000 Multiplace
Indications for use	Air or Gas Embolism Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning Clostridal Myositis and Myonecrosis (Gas Gangrene) Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias Decompression Sickness Enhancement of Healing in Selected Problem Wounds Exceptional Blood Loss (Anemia) Intracranial Abscess Necrotizing Soft Tissue Infections Osteomyelitis (Refractory) Delayed Radiation Injury (Soft Tissue and Bony Necrosis) Skin Grafts & Flaps (Compromised) Thermal Burns"	SAME
Number of Patients	6-18	3-8
Where used	Hospitals & Clinics	SAME
Fire Suppression	Included	SAME
Standards met	ASME Boiler and Pressure Vessel Code, Section VIII, Division I; and ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy.	SAME Plus NFPA 99 requirements for hyperbaric facilities and IEC60601 (UL2601)

6. Conclusion

In all respects, the "Model 5000 Multiplace" Hyperbaric Therapy Systems are substantially equivalent to one or more clinical multiplace hyperbaric chambers that are legally marketed for the conduct of hyperbaric oxygen therapy. Testing and certifications demonstrate that the device meets the standards referenced above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. Daniel Kamm
HyperTec, Inc.
c/o Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K002794
"Model 5000 Multiplace" Hyperbaric Therapy Systems
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: September 5, 2000
Received: September 7, 2000

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html"..

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K002794

Device Name: HyperTec "Model 5000 Multiplace" Hyperbaric Therapy System.
Indications for Use: All of the contemporary substantially equivalent systems listed as predicate devices are used for the same indications as listed in the Hyperbaric Oxygen Therapy: Committee Report, Undersea and Hyperbaric Medical Society, Inc., Revised 1999:
"The following indications are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee.

- Air or Gas Embolism
- Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
- Clostridal Myositis and Myonecrosis (Gas Gangrene)
- Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias
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- Thermal Burns"

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002794

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)